

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: MCNEIL CONSUMER	:	MDL NO. 2190
HEALTHCARE, ET AL., MARKETING	:	
AND SALES PRACTICES LITIGATION	:	
	:	
Applies to:	:	
ALL ACTIONS	:	

MEMORANDUM

McLaughlin, J.

July 13, 2012

This multidistrict litigation arises out of quality control problems at the defendants' facility manufacturing over-the-counter healthcare products in Fort Washington, Pennsylvania, which led to a series of recalls of those products. The named plaintiffs assert claims for economic loss on behalf of a putative nationwide class against Johnson & Johnson ("J&J"), McNeil Consumer Healthcare ("McNeil"), and four of their executives. The plaintiffs allege that they overpaid for the defendants' products as a result of the recalls and the defendants' scheme to conceal or downplay the scope of the quality control problems.

The defendants, who have offered a coupon or cash refund to consumers who purchased recalled drugs, have moved to dismiss the operative complaint, and assert that the named plaintiffs lack constitutional standing and have not met the applicable pleading standard. The Court will grant the defendants' motion because the plaintiffs have not pled facts that show a cognizable injury in fact, which is required to

confer Article III standing.

I. Procedural Background

This litigation resulted from the consolidation of ten individual actions filed around the country. Haviland v. McNeil Consumer Healthcare, No. 10-2195, was filed in this Court on May 12, 2010, asserting economic injuries arising out of the April 30, 2010 recall of over-the-counter children's drugs by McNeil, a part of the J&J "Family of Companies." Eight additional cases, also arising out of the April 2010 recall, were filed in district courts around the country.¹ All cases asserted claims for economic injury only, with the exception of Rivera v. Johnson & Johnson, which initially also asserted claims for physical injury. On October 8, 2010, the Judicial Panel on Multidistrict Litigation transferred the above-referenced cases to this Court, where they and all future "tag-alongs" were consolidated into MDL Number 2190.

The plaintiffs filed their initial consolidated class

¹ Those cases include: Roberson v. McNeil Consumer Healthcare, Civil No. 10-5560 (N.D. Ill.); Rivera v. Johnson & Johnson, Civil No. 10-5579 (C.D. Cal.); Nguyen v. McNeil Consumer Healthcare, Civil No. 10-5580 (N.D. Ill.); Michaud v. McNeil Consumer Healthcare, Civil No. 10-5587 (N.D. Ill.); Smith v. McNeil Consumer Healthcare, Civil No. 10-5654 (N.D. Ill.); Burrell v. McNeil Consumer Healthcare, Civil No. 10-5656 (N.D. Ill.); DeGroot v. McNeil Consumer Healthcare, Civil No. 10-5657 (N.D. Ill.). Two tag-along cases were later transferred to this Court: Coleman v. McNeil Consumer Healthcare, Civil No. 10-6905 (S.D. Ohio) and Harvey v. Johnson & Johnson, Civil No. 11-2363 (E.D. Mo.).

action complaint ("CAC") on January 12, 2011, adding allegations relating to behavior prior to the April 30, 2010 recall, expanding the number of named plaintiffs, and dropping all claims for physical injury. The CAC had named the above defendants as well as a number of contractor companies involved in a recall of Motrin IB,² and numerous other J&J and McNeil executives and board members. The defendants moved to dismiss for lack of standing and other pleading deficiencies in April 2011, and after oral argument in June 2011, the Court granted the motions to dismiss. Docket No. 47 ("Mem. Op."), available at In re McNeil Consumer Healthcare Mktg. & Sales Practices Litig., MDL No. 2190, 2011 WL 2802854 (E.D. Pa. July 15, 2011). In that opinion, the Court concluded that the named plaintiffs lacked standing as to all claims because they had not suffered an injury in fact, and because they had not established that the actions of the contractor defendants caused any economic injury. Mem. Op. 25 ("Even assuming that the 'serious problems' identified above encompass the allegations of specific product recalls and FDA citations, the plaintiffs fail to allege any personal harm arising therefrom."). The contractor defendants were dismissed with prejudice, but all claims against J&J, McNeil, and their employees were dismissed without prejudice.

² These defendants were Inmar, Incorporated; WIS International; Carolina Logistics Services, LLC; and Carolina Supply Chain Services, LLC.

The plaintiffs were given leave to file an amended complaint within thirty days, and the instant Second Amended Civil Consumer Class Action Complaint ("SAC") was filed on August 15, 2011. The defendants moved to strike certain matter from the complaint and moved separately to dismiss the complaint for lack of standing and for failure to state a claim. The Court held oral argument on the defendants' motions on January 19, 2012.

II. Facts as Alleged in the SAC

The SAC alleges that J&J and McNeil, along with four of its current and former executives,³ conspired to conceal quality control problems beginning in at least December 2008 and affecting the quality of medications sold over-the-counter and manufactured, among other places, at McNeil's facility in Fort Washington. The twenty-four named plaintiffs⁴ argue that the existence and concealment of these quality control problems led them to pay inflated prices because of J&J's reputation for safe

³ The executives named in the SAC are William Weldon (CEO of J&J); Colleen Goggins (former Chairman of the J&J Consumer Healthcare Segment and member of the Group Operating Committee ("GOC") of J&J); Rosemary Crane (GOC member responsible for McNeil and Company Group Chairman); and Peter Luther (President and CEO of McNeil). The SAC drops claims previously asserted in the CAC against other board members.

⁴ The number of named plaintiffs fell from twenty-seven in the CAC to twenty-four in the SAC. The SAC does not include allegations from earlier named plaintiffs Janelle Bridges, Ethel Ingram, or Kylie Hess. CAC ¶¶ 29, 38, 51. Otherwise, all named plaintiffs in the SAC are named in the CAC.

and effective medications.

The defendants were aware of the quality control issues at McNeil but ignored them and concealed their nature from consumers despite their "red flags." Only in April 2010 did the defendants reveal that the FDA had cited McNeil for manufacturing problems after an inspection of the Fort Washington facility revealed deficiencies, despite the defendants' awareness of the "serious degradation of the quality and condition" of all the products manufactured there. SAC ¶¶ 4-10.

The main additions to the SAC are descriptions of the specific products that the named plaintiffs purchased, with National Drug Code ("NDC") designations where the plaintiffs have that information. When that information is not available or is incomplete, the SAC avers that the named plaintiff "is not able to provide a complete listing of the products [s]he purchased, or the complete identification of them (including the NDCs, lot numbers, and expiration dates) due to the passage of time and having discarded the Subject Products because of the recall." SAC ¶¶ 26, 29-34, 36, 39, 41-42, 45.

A. Quality Control Concerns and Recalls

The named plaintiffs are individuals from fourteen states and Ontario, Canada who bring claims on behalf of themselves and a putative nationwide class of consumers who purchased the "Subject Products" between at least December 2008

and the present.⁵ They allege that management-level employees of

⁵ The SAC describes the "Subject Products" as "substandard and defective" and "not of the quality and condition as represented at the time of sale." SAC ¶ 2. The plaintiffs state that the "Subject Products" list has not changed from the CAC to the SAC. Ltr. from Donald E. Haviland, Jr., to the Court, Aug. 24, 2011, Decl. of Andrew D. Schau, Def. Mot. to Dismiss Ex. 1, ECF No. 52 ("Haviland Ltr.") ("It is incorrect that the list of Subject Drugs has expanded."). However, the descriptions of "Subject Products" in exhibits to the SAC and CAC do appear to differ.

According to the SAC, the Subject Products consist of "all forms (including all sizes, dosages, and flavors)" of the following drugs: Motrin IB Caplet; Motrin IB Tablet; Junior Strength Motrin; Children's Motrin Suspension; Concentrated Motrin Infants' Drops; Extra Strength Tylenol Caplet; Extra Strength Tylenol Cool Caplet; Extra Strength Tylenol EZ Tab; Extra Strength Tylenol PM Caplet; Extra Strength Tylenol PM Geltab; Extra Strength Tylenol Rapid Release Gelcap; Extra Strength Tylenol Tablet; Regular Strength Tylenol Caplet; Tylenol 8 Hour Caplet; Tylenol 8 Hour Extended Release Caplet; Tylenol Allergy Multi-Symptom Cool Burst Caplet; Tylenol Allergy Multi-Symptom Nighttime Cool Burst Caplet; Tylenol Arthritis Caplet; Tylenol Arthritis Geltab; Tylenol Arthritis Pain Caplet; Tylenol Arthritis Pain Geltab; Tylenol Cold Head Congestion Day/Night Cool Burst Caplet; Tylenol Cold Head Congestion Daytime Cool Burst Caplet; Tylenol Cold Head Congestion Nighttime Cool Burst Caplet; Tylenol Cold Head Congestion Severe Daytime Cool Burst Caplet; Tylenol Cold Multi-Symptom Daytime 8 oz. Citrus Burst Liquid; Tylenol Cold Multi-Symptom Daytime Cool Burst Caplet; Tylenol Cold Multi-Symptom Nighttime 8 oz. Cool Burst Liquid; Tylenol Cold Multi-Symptom Severe 8 oz. Cool Burst Liquid; Tylenol Cold Multi-Symptom Severe Daytime Cool Burst Caplet; Tylenol Day & Night Value Pack; Tylenol Sinus Congestion & Pain Day/Night Cool Burst Caplet; Tylenol Sinus Congestion & Pain Daytime Cool Burst Caplet; Tylenol Sinus Congestion & Pain Nighttime Cool Burst Caplet; Tylenol Sinus Congestion & Pain Severe Daytime Cool Burst Caplet; Children's Tylenol Plus Cold Suspension; Children's Tylenol Meltaway Tablet; Children's Tylenol Dye Free Suspension; Children's Tylenol Plus Cold MS Suspension; Children's Tylenol Pediatric Suspension; Children's Tylenol Plus Cold/Allergy; Children's Tylenol Plus Cough & Runny Nose; Children's Tylenol Plus Cough/ST Suspension; Children's Tylenol Plus Dye Free Cold & Cough Suspension; Children's Tylenol Plus Dye Free Cold & Stuffy Nose Suspension; Children's Tylenol Plus Dye Free Multi-Symptom Cold Suspension; Children's Tylenol

J&J and McNeil were aware of serious manufacturing and quality control problems at McNeil plants through, at a minimum, the FDA's April 30, 2010 report and the filing of shareholder derivative lawsuits against J&J. In response to those lawsuits a "Special Committee" of the J&J board investigated these issues and made a report on June 27, 2011, detailing the existence of these problems and the awareness of management-level officials of these issues. SAC ¶¶ 6, 8, 9.

Plus Flu Suspension; Children's Tylenol Plus Cold & Allergy Suspension; Children's Tylenol Plus Cold Suspension; Children's Tylenol Plus Cough & Runny Nose Suspension; Children's Tylenol Plus Cough & Sore Throat Suspension; Children's Tylenol Suspension - Hospital; Children's Tylenol Suspension - Sample; Children's Tylenol Suspension; Concentrated Tylenol Infants' Drops; Concentrated Tylenol Infants' Drops - Sample; Concentrated Tylenol Infants' Drops - Hospital; Concentrated Tylenol Infants' Drops Dye Free; Infants' Tylenol Drops; Infants' Tylenol Dye Free Suspension; Infants' Tylenol Suspension; Benadryl Allergy & Cold Kaps; Benadryl Allergy Plus Cold Kaps; Benadryl Allergy Plus Sinus Headache Kaps; Benadryl Allergy Tablet; Benadryl Allergy Ultratab; Benadryl Severe Allergy Plus Sinus Headache Caplet; Children's Benadryl Allergy Sugar-Free Dye-Free Liquid; Children's Benadryl Allergy Fastmelt Tablet; Extra Strength Rolaid Tablet; Multi Symptom Rolaid Tablet; Original Rolaid Tablet; Rolaid Extra Strength Plus Gas Softchews; Rolaid Extra Strength Softchews; Rolaid Multi-Symptom Plus Anti-Gas Softchews; Rolaid Multi-Symptom Tablet; Simply Sleep Mini Caplet; St. Joseph Aspirin Chewable Tablet; St. Joseph Aspirin Enteric Coated Tablet; Children's Zyrtec Sugar-Free Dye-Free; Pepcid Complete Chewable Tablet; Original Strength Pepcid AC; Sudafed PE Day & Night Cold Coated Caplet; Sudafed PE Cold & Cough Coated Caplet; Sudafed PE Non-Drying Sinus Coated Caplet; Sudafed PE Severe Cold Coated Caplet; Sudafed PE Nighttime Cold Coated Caplet; Sudafed PE Sinus Headache Coated Caplet; Sudafed PE Triple Action Coated Caplet; Sudafed 24 Hour Pseudoephedrine HCl Extended-Release Tablet; Sinutab Sinus Coated Caplet; Topamax Tablet; Risperdal Tablet; Risperidone Tablet. SAC ¶ 2; Id. Ex. A.

The FDA report forced the defendants to admit publicly the "observations" made at the Fort Washington plant by investigators between April 19th and 30th of 2010 of failures to meet current good manufacturing practices ("cGMP"). The cGMP issues that the FDA identified included production control failures resulting in inconsistent drug strength, quality, and purity; inclusion of known contaminants; inadequate cleanliness and record keeping; failure to follow written process control procedures; inadequate training; and failure to issue regular reports on quality. Id. ¶¶ 312-13; Apr. 30, 2010 FDA Report, Id. Ex. G.

The day the FDA report was released, the Fort Washington facility was closed and McNeil announced a recall due to quality control issues but "not . . . on the basis of adverse medical events." The recall applied to forty types of products manufactured there including certain lots of liquid infant and children's products, such as Tylenol, Motrin, and Benadryl, due to particulate contamination and superpotency concerns. Congress conducted a series of hearings in May and September 2010 in response to the recall announcement. SAC ¶ 232 & Ex. I; Id. ¶¶ 256-57, 320-33.

The SAC also reviews a series of other recalls conducted by McNeil between 2008 and 2011 in response to quality concerns at McNeil's plants in Fort Washington and elsewhere.

The defendants recalled some lots of Motrin, Tylenol, Benadryl, Roloids, Simply Sleep, St. Joseph Aspirin, Pepcid, Mylanta, Alternagel, Sudafed, Sinutab, Topamax, Risperdal, and Risperidone. Some of these recalls appear to have been conducted at the consumer level with refunds offered to consumers; others were conducted at the retail or wholesale level, and consumers were informed that the products were safe to use. The recalls were conducted for a variety of reasons, including concerns over subpotency, musty odors, erroneous or defective packaging, product texture, the presence of particulate matter, and the failure to disclose alcohol as an ingredient. Id. ¶¶ 197-98, 200-01, 207, 241, 251-54, 267-69, 271-301.⁶

⁶ The SAC refers repeatedly to "Subject Products" without identifying which products were subject to a recall. The unifying characteristic of "Subject Products" is that each was produced at a facility that has, at some point, been subject to manufacturing problems of the kind identified by the FDA at Fort Washington in April 2010. According to the Court's understanding of the material in the complaint, including McNeil recall announcements appended to the SAC, the Subject Products that were recalled include:

- 4/30/2010:
 - Concentrated Tylenol Infants' Drops
 - Children's Tylenol Suspensions
 - Children's Tylenol Plus Suspensions
 - Concentrated Motrin Infants' Drops
 - Children's Motrin Suspensions
 - Children's Motrin Cold Suspensions
 - Children's Zyrtec
 - Children's Benadryl Liquid
- 6/15/2010:
 - Tylenol Extra Strength Rapid Release Gels
 - Benadryl Allergy Ultratab

The plaintiffs aver that all of the products, not just those that were recalled at the consumer level, suffered from the cGMP issues that made them less valuable. SAC ¶ 376.

B. Deficiencies in the Recall Program

For those products that were recalled starting in April 2010, the plaintiffs claim numerous deficiencies with respect to the nature and quality of the recall, including the recall announcement itself, which the plaintiffs claim was deliberately

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- 7/8/2010:
 - Tylenol Extra Strength
 - Tylenol PM
 - Children's Tylenol Meltaways
 - Benadryl Allergy Ultratab Tablets
 - Motrin IB
 - 8/10/2010:
 - Pepcid Complete Acid Reducer
 - Original Strength Pepcid AC
 - 10/18/2010: Tylenol 8-Hour
 - 12/9/2010: Roloids Softchews

SAC Ex. I at McNeil-MDL-0000087-89; SAC ¶ 269.

With reference to the McNeil recall website referenced in the SAC (www.mcneilproductrecall.com), the Court was able to identify two additional recalls that potentially match the named plaintiffs' allegations: an additional recall of Tylenol 8-Hour (3/29/11) and of Tylenol Extra Strength Caplets (6/28/11). See http://www.mcneilproductrecall.com/page.jhtml?id=/include/replacement_coupon.inc (form for consumers to request refund or coupon).

Where the plaintiffs' averments are consistent with but do not allege a recall definitively, the Court assumes that those drugs were recalled and are thus subject to the refund program.

chosen to minimize consumer awareness of the program. SAC ¶ 5.⁷ The refund offers coupons or cash refunds for consumers who contact the defendants by telephone or submit an online form with NDC numbers, lot numbers, and expiration dates to determine whether or not their drugs are subject to recall.⁸ The offer does not note how the refund amounts are to be calculated. Id. ¶¶ 369-70.

The plaintiffs allege that the recall was inadequate because the refund offers did not fully and fairly compensate them for the costs they incurred as a result of the defendants' actions. Further, the plaintiffs allege that the J&J website "specifically advise[d]" individuals to discard used products, rendering them unable to provide the information required to obtain a refund. Id. ¶¶ 372, 377, 389. Plaintiffs' counsel,

⁷ The SAC adds an exhibit consisting of printouts from a J&J blog including an exchange between a purported consumer (not a named plaintiff) and a J&J executive regarding the choice of timelines for the discussion of the recall announcement. See SAC Ex. I at McNeil-MDL-0000003-0000011.

⁸ The CAC had alleged that J&J had improperly encouraged plaintiffs to discard their products, thereby interfering with the plaintiffs' ability to record or retain the identifying information necessary to determine whether their product had been recalled. CAC ¶ 13. The SAC's allegations, in contrast, are that plaintiffs disposed of the products they purchased "because of the recall." See, e.g., SAC ¶ 26. The SAC also alleges generally that the defendants' failure to "properly assess the nature and scope of the problem" with quality control "directly caused" the named plaintiffs "to continue to use, consume, and discard Subject Products despite their defective condition." Id. ¶ 11.

however, conceded that J&J made no specific instructions to discard recalled products, but instead that the named plaintiffs had discarded products as a result of what they heard in media reports or for other reasons. Tr. Hr'g 1/19/12 at 44-45.

The plaintiffs attach McNeil communications to the SAC to argue that (1) only the "average retail price" was offered as a refund; (2) the refund offer excluded sales taxes; and (3) the amounts offered were changed, demonstrating a failure to "properly value the retail prices paid" by the plaintiff class members; and (4) representatives "pushed worthless coupons" for items that would no longer be sold at retail. Id. ¶¶ 386-88 & Ex. I at McNeil-MDL-0000092. Additional costs claimed by the plaintiffs include those related to disposal, transportation to purchase replacement products, medical expenses incurred as a result of concerns of adverse reactions, and time spent investigating the recall. See id. ¶¶ 25-46.⁹

C. Conspiracy Allegations

McNeil's quality control problems allegedly were caused by a series of oversight cutbacks instituted by J&J upper management, were longstanding, and were concealed purposefully.

⁹ The SAC repeats allegations from anonymous blog poster "Aaron L." and nonparty Evan D. Owen that cash refunds were inadequate and the representatives handling refunds who were reachable were "data collectors and coupon issuers." SAC ¶¶ 383, 385.

1. Shareholder Suits and Special Committee Report

The SAC references a series of shareholder suits brought against J&J directors between February and November 2010 and the report of a Special Committee of the Board of Directors tasked with investigating these claims.¹⁰ SAC ¶¶ 342-67. The defendants separately moved to strike these allegations under Federal Rule of Civil Procedure 12(f) as impertinent to the instant suit. Some of the suits alleged malfeasance by nonparties to this action, "off-label promotion" of J&J drugs, kickback schemes entered into with surgeons, and bribery of the Iraqi government. Others related to the issues described above, including insufficient quality controls at plants, FDA investigations, and product recalls. Except to the extent that these allegations go to the notice by the Board of Directors of cGMP issues at McNeil plants, this material is irrelevant and the Court will not go into greater detail regarding the shareholder suits and Special Committee investigation.

2. Earlier Quality Control Problems

Until 2002, J&J had a reputation for high quality control standards, although it was criticized by the FDA from

¹⁰ The Special Committee Report is not attached to the SAC, but the plaintiffs' characterization thereof is consistent with their general allegations of inadequate oversight and quality control as a result of decentralized governance, which are largely unchanged from the CAC. SAC ¶ 341.

time to time. Decisions by J&J management to conduct "repeated layoffs of experienced quality control staff" led to a deterioration of quality at McNeil plants in Fort Washington and Las Piedras, Puerto Rico. In spite of FDA concerns, McNeil quality control management overlooked or demanded manipulation of troublesome test results, and sold problematic products at full retail value. In 2007, for example, cuts to the corporate compliance department were approved, which resulted in a reduction in the quality of internal investigations. Indeed, the 2010 report was not the first time McNeil was aware of issues with its manufacturing and quality control procedures. The FDA noted in reviews in February 2008 and June 2009 that McNeil was not conducting adequate investigations. The FDA issued an Enforcement Report in January 2006 referring to foreign substances and subpotent dosages found in over-the-counter products sold by McNeil for children's use. SAC ¶¶ 175-85, 187-90, 316-19.

3. Individual Defendants

The plaintiffs allege the personal involvement of four executives in a conspiracy to downplay the seriousness of the quality control problems at McNeil plants. These individuals had personal knowledge of and responsibility for the deterioration in quality control at McNeil plants.

William Weldon, CEO and Chairman of J&J from April 25,

2002 through the relevant period, "had personal knowledge of the deplorable conditions" at the plants and "was responsible for the decisions that led to the degradation in quality" there. Weldon "opted to continue J&J's decentralized management and operational structure" when he joined. He was advised of J&J's compliance problems in 2005 or 2006, but decided to make significant cuts to its corporate compliance group in 2007 instead of improving it. When the 2010 recalls were occurring, he stated publicly that the issue was "not a systemic problem" at J&J. In testimony before Congress, he admitted the 2009 recall of Motrin IB--characterized as a "phantom recall" because it was conducted through contractor purchases of the product from stores and not announced to the public--should have been handled differently. The SAC adds the allegation that Weldon "knew or should have known" that J&J's decentralization strategy would result in cGMP problems. Id. ¶¶ 57, 109, 112, 114, 118, 191, 332.

Colleen Goggins is the former Worldwide Chairman of the J&J Consumer Healthcare Segment who left the company in early 2011. She reported directly to Weldon as part of the Group Operating Committee at J&J. Similar allegations are made against her with respect to her role in the cost-cutting in quality control processes and her actual or constructive knowledge that it caused the quality control problems identified at J&J. Finally, Goggins testified before Congress regarding the 2009

Motrin "phantom recall" and was contrite, but downplayed the problems as "minute." Id. ¶¶ 58, 115, 119, 325-27.

Peter Luther is the former president of McNeil, who held that post from January 2009 to April 2010. He served in a variety of J&J subsidiary executive posts between 1991 and 2010. He is alleged to have had personal knowledge of the conditions in the McNeil plants. He authorized the Motrin "phantom recall" and met with FDA officials to discuss their concerns over McNeil's noncompliance with regulations. On May 13, 2010, he signed a document containing "common questions" for consumers stating that they were eligible for refunds for the "average retail price" or replacement coupons. Luther is noted as having "introduced quarterly quality reviews and requested more substantive quality presentations." Id. ¶¶ 60, 121, 202, 308, 341, 386.

Rosemary Crane was a Company Group Chairman and chair of the Corporate Group Operating Committee for J&J, who reported directly to Weldon and was responsible for McNeil. In her role with the committee, she granted approval before any changes were made to the "operation or management of the plants." She is alleged to have been aware of the conditions in the plants, and of the fact that J&J's decentralization push would result in the cGMP problems that occurred. Id. ¶¶ 59, 97-98, 119.

D. Factual Allegations of Individual Named Plaintiffs

The SAC contains factual allegations specific to each of the twenty-four named plaintiffs, and describes the products each purchased and the approximate price he or she paid. The SAC then describes the NDC information of purchased products where it is available (or why the plaintiff is unable to provide such information), why each plaintiff did or did not contact the defendants about a refund, and the relief sought.

In its earlier opinion, the Court noted that the named plaintiffs did not fall into a "monolithic category," and that separate analyses of each plaintiff would be necessary upon any amendment. Mem. Op. 35-36. In concluding that the CAC had identified injuries that were "abstract and hypothetical, rather than distinct and palpable," the Court stated its confusion over how the allegations regarding the defendants' behavior were connected to an injury suffered by a named plaintiff. Id. at 26-27 (citing Danvers Motor Co., Inc. v. Ford Motor Co., 432 F.3d 286, 290-91 (3d Cir. 2005)).

Although each named plaintiff's allegations will be detailed below, the averments of the SAC lend themselves to the grouping of named plaintiffs into one or more of the following categories:

- (1) Purchasers of non-recalled products who consumed them or have failed to allege how they suffered injury as a result of purchasing them;

- (2) Purchasers of recalled products who have sought a refund or coupon and received one, or are waiting to receive one because of the terms of the offer;
- (3) Purchasers of recalled products who are eligible for, but have not sought, a refund; and
- (4) Plaintiffs who discarded products they purchased and thus no longer possess the information required to determine whether they are entitled to a refund.

With these categories in mind, the Court discusses the allegations of each named plaintiff identified in the SAC.

1. Brittney Spivey

In 2010, Spivey, a Florida resident, purchased Children's Motrin Grape, 4 oz., Tylenol Infant's Drops, Cherry Flavor, 1 oz., and Tylenol Infant's Drops, 0.5 oz, each of which was subject to the April 30, 2010 recall. She paid between \$8 and \$9 for each, plus tax. She called the telephone line established by the defendants and requested a refund, but was told that she would have to return the products or package them and send them to McNeil (which the representative "pressed" her to do). She knows that she can request a refund now, but at the time of her phone call she concluded that it would be "too much effort." She seeks the cost of replacement products, transportation expenses to obtain them, medical expenses "related to concerns about ingestion" of the products, and time spent investigating the recall and speaking to professionals about it. SAC ¶ 25.

2. Joyce Taylor

Taylor, an Ohio resident, purchased at least nineteen products for children and adults but is unable to provide a complete list or identify them via NDC or lot numbers "due to the passage of time and having discarded the Subject Products because of the recall." She paid approximately \$6 to \$7. Some of the products she purchased may have been subject to a recall, including Children's Tylenol Cold & Fever, Children's Tylenol, Children's Motrin Suspensions, Concentrated Motrin Infants' Drops, Extra Strength Tylenol Caplets, Children's Tylenol Plus Suspension, and Children's Benadryl Allergy Liquid. She claims she was not aware of a refund offer prior to becoming involved in the lawsuit.¹¹ She seeks the costs of product replacement, transportation expenses, and time spent investigating the recall. Id. ¶ 26.

3. John Thrasher

Thrasher is an Arizona resident who purchased two bottles of Children's Tylenol, Oral Suspension, Grape Splash Flavor, 4 oz.; both bottles were subject to the recall. In

¹¹ Many of the named plaintiffs state that they did not know about the refund program until the instant suit made them aware of it. All named plaintiffs appear to be aware, at this time, that a refund is available for all products recalled from consumers. See Tr. Hr'g 1/19/12 at 7:20-23 (defendants' concession that all products so recalled are subject to the refund program).

January 2010, he complained to someone at McNeil that he suffered "adverse effects" after taking the medicine. He again contacted McNeil in June 2010 "to obtain information regarding an earlier call he thought he had placed to McNeil (but it was instead to his pharmacy)" regarding a medical complaint he had made in connection with his use of the product. He read about the recall on the internet, but was not aware of any refund offer and has not sought one. He seeks out-of-pocket medical expenses "relating to the aforesaid adverse affects [sic]" in the amount of \$300-400. Id. ¶ 27 & Ex. B.¹²

4. Jason & Jody Munn

The Munns, Washington residents, purchased Children's Motrin, Children's Tylenol Bubble Gum Meltaway Tablets, and Sudafed PE Cold and Cough for \$6 to \$8 plus tax. They reported to the FDA that their child had suffered an adverse event after taking the Motrin. The FDA told them that the Motrin product had been recalled. They were then contacted by a J&J representative in May or early June 2010, who requested that they return the unused portion of the Children's Motrin for testing, but they

¹² It is unclear to the Court why this averment and similar allegations appear in the SAC when the plaintiffs bring claims solely for economic losses. See Haviland Ltr. ("[I]t is incorrect that additional 'claims' are made on behalf of plaintiffs who suffered personal injury."). Even so, Thrasher does not allege that any "adverse effects" were caused by the quality control issues at McNeil.

declined. They were offered a coupon for a replacement bottle but did not accept. They have not requested a refund for any of the products they purchased. They seek the cost of replacement products, transportation costs, medical expenses related to "concerns about ingestion" of the products (\$600), and compensation for time spent investigating the recall. Id. ¶ 28.

5. Edna Scott

Scott purchased at least eleven children's and adult products manufactured by the defendants for between \$5 and \$9, but cannot provide a complete list of the products she purchased because she discarded many of them. Among the products she lists that may have been subject to recall are Tylenol Meltaways, Children's Zyrtec Syrup, Tylenol Extra Strength, Motrin IB, and Children's Tylenol Plus Cold. She contacted the defendants to request a refund, was told she needed to send receipts, and did so, but she does not specify the products for which she requested a refund. She did not hear back from the defendants. She then visited the McNeil website "and attempted to obtain a refund and further information . . . regarding a refund," but "subsequently gave up her attempts." She seeks replacement costs, transportation expenses, medical expenses, and compensation for time spent investigating the recall. Id. ¶ 29.

6. Amber Coleman

Coleman, an Ohio resident, purchased at least seven children's medicines for between \$6 and \$7, including Concentrated Tylenol Infants' Drops, Concentrated Motrin Infants' Drops (for which she has identifying information), and Children's Motrin, Tylenol, and Zyrtec (for which she does not have identifying information because she discarded these products "due to fear of accidental usage"). She was aware of the recall but did not contact the defendants for a refund because she did not know about it until the instant suit. She seeks the cost of replacement products, transportation costs, and compensation for time spent investigating the recall. Id. ¶ 30.

7. Brandie Carroll

Carroll, a North Carolina resident, purchased Concentrated Tylenol and Motrin Infants' Drops and Children's Benadryl Allergy Liquid for approximately \$6. All three may be subject to a recall but she lacks identifying information because she discarded the products. She was not aware of a refund until the instant suit and has not contacted the defendants to obtain one. She seeks replacement costs, transportation expenses, and compensation for time spent investigating the recall. Id. ¶ 31.

8. Daniel Pack

Pack, a resident of Ohio, purchased at least sixteen

children's or adult medicines for between \$5 and \$12. He has identifying information for many of them, including Children's Tylenol and Tylenol Plus Suspensions, Motrin Suspensions, Zyrtec, and Benadryl Liquid. He also purchased some Motrin Suspensions, Extra Strength Tylenol, Benadryl Caplets, Roloids Tablets, Sudafed Caplets, and prescription Topamax tablets¹³ for which he does not have identifying information because the items were discarded.

He requested a refund from the McNeil website in October 2010, but did not have sufficient information to obtain refunds for all products he purchased, and believed that he could only obtain a refund for five products. He received a refund for \$40 for "some of the recalled children's products" that he alleges does not cover the full price of all of the products that he purchased. He seeks the cost of replacement products, transportation expenses, and time spent investigating the recall. Id. ¶ 32.

9. Gene Renz

Renz, a Pennsylvania resident, purchased sixteen children's and adult medicines, but cannot provide identifying information for many of them because the items were discarded due to the recall and his fear of accidentally using them. Among the

¹³ Topamax is a prescription medication manufactured by a nonparty J&J subsidiary.

products he purchased that appear to have been recalled are Tylenol Infants' Drops and Children's Benadryl Allergy Liquid. He also purchased Children's Motrin Suspension, Extra Strength Tylenol Tablets, Children's Tylenol Plus, Infant's Tylenol Suspension, Benadryl, and Sudafed. He paid \$7-8 for the children's products and \$10-14 for the adult products. He was not aware of the refund offer until the instant suit and has not requested one. He seeks replacement costs, transportation expenses, and investigation costs. Id. ¶ 33.

10. Justin Michaud

Michaud, a Massachusetts resident, purchased five Children's Tylenol, Zyrtec, and Benadryl products and one Adult Tylenol Allergy product for between \$6 and \$12. He also alleges that he purchased at least one bottle of Zyrtec per month dating back to 2008. He possessed lot and NDC information regarding one of his children's Zyrtec purchases, which was subject to a recall. He requested a refund over the website for Zyrtec and received a \$13 check, which covered the full purchase price. By email, he requested refunds for all prior purchases of Zyrtec but did not hear back. He has not requested refunds for any of the other products, and was not aware that the Tylenol Allergy product had been recalled. He seeks replacement costs, transportation costs, and investigation costs. Id. ¶ 34.

11. Dana Rivera

Rivera, a California resident, purchased five medicines for approximately \$7 each, including Children's Tylenol Plus suspensions, Children's Motrin Suspension, and Concentrated Tylenol Infants' Drops. She has identifying information for all of these products, several of which may have been subject to recall. She worked in a Rite-Aid and assisted in the removal of some of these products from the shelves, but has not requested a refund. She seeks replacement costs, transportation costs, and reimbursement for time spent investigating the recall. Id. ¶ 35.

12. Candy Angel

Angel, a Kentucky resident, purchased four Tylenol products for which she paid between \$7 and \$12, including two Concentrated Tylenol Infants' Drops, Extra Strength Tylenol, and Tylenol Arthritis. She alleges that she purchased additional products but cannot identify them because the products were discarded. She has identifying information for the Infants' Drops that might demonstrate that they were recalled. She learned of the recall from her mother in May 2010 but has not requested a refund. She seeks replacement and transportation costs. Id. ¶ 36.

13. Catherine Roselli

Roselli, a New Jersey resident, purchased Children's

Tylenol and Motrin Suspensions for approximately \$9.40 and has identifying information for the products, but was unaware of any refund until the instant suit and has not requested one. She does not specify the relief she seeks. Id. ¶ 37.

14. John Smith

Smith, an Illinois resident, purchased Children's Tylenol Oral Suspension, Cherry Flavor, 4 oz., for between \$6 and \$7. He learned about the recall on the radio and contacted the J&J telephone line to inquire about a refund. He was told that he was eligible for a replacement coupon and would receive one in the mail, but has not yet received one.¹⁴ He seeks replacement costs, transportation expenses, and investigation costs. Id. ¶ 38.

15. Landy Nguyen

Nguyen, an Illinois resident, purchased at least six products for between \$8.50 and \$12.50, and has identifying information for two of them that may have been subject to a recall, including Children's Tylenol Plus and Motrin Suspensions. She also purchased Extra Strength Tylenol Rapid Release Gelcaps;

¹⁴ The McNeil website notes that purchasers who accept replacement coupons will receive them "when the product becomes available again." SAC Ex. I at McNeil-MDL-0000029. Smith does not allege that Children's Tylenol Oral Suspension 4 oz., Cherry Flavor, is available at retail currently or has been since he requested the coupon. Counsel conceded that Smith elected to receive the coupon instead of money. Tr. Hr'g 1/19/12 at 54.

Children's Tylenol Cough & Sore Throat and Cough & Runny Nose; Children's Benadryl Allergy Bubblegum Liquid; and Children's Motrin, for which she does not have identifying information because she discarded the products.

Nguyen, who "speaks with an Asian accent," called McNeil in May and June 2010 to inquire about the recall, but was unable to make herself understood to the call representatives and felt as though "she was getting the run-around." She asked for another representative to call her back but did not receive a call. She did not contact the defendants again. She seeks replacement costs, transportation expenses, and investigation costs. Id. ¶ 39.

16. Maura McDaid

McDaid, a Pennsylvania resident, purchased four products and has lot and expiration-date information for all of them. These include Children's Tylenol, Children's Motrin, and two forms of Concentrated Infant Drops, for which she paid between \$8 and \$10. She alleges that Tylenol, in particular, was the "'go-to' drug for her family" and that she "knowingly paid extra . . . because of the reputation and commitment for safety." She learned of the recall through local television but has not requested a refund, because she is "concerned about the significant amount of 'red-tape' involved and knew that she did not have receipts" for many of the products. She seeks

replacement, transportation, investigation, and disposal costs.¹⁵

Id. ¶ 40.

17. Rhonda Mannara

Ms. Mannara, a New York resident, purchased Children's Motrin and Children's Tylenol for her grandchildren but discarded the products and does not have identifying information for them and is not sure what she paid. She has not requested a refund. She does not specify the relief she seeks. Id. ¶ 41.

18. Donna Varner

Varner, a Pennsylvania resident, purchased at least seventeen children's and adult medicines for "in excess of \$100." Several of these products may be subject to the recall given the identifying information she has (Concentrated Motrin Infants' Drops, Children's Motrin, Children's Zyrtec, and Children's Benadryl), but she does not have information for others because she discarded the products. She was aware of the recall but not the refund for the children's products, and was unaware of any recall for the adult products. She has not requested a refund. She seeks replacement, transportation, and investigation costs. Id. ¶ 42.

¹⁵ The McNeil refund offer does not require that consumers provide receipts.

19. Emile & Amber Roberson

The Robersons, Texas residents, purchased Concentrated Tylenol Infants' Drops (in three forms) and Children's Benadryl Allergy Liquid (all for \$6-7), and two forms of Benadryl Allergy Ultra Tab (\$12-14). They requested a refund in May 2010 through the website for the children's medicines. They received two refund checks for the children's medicines in a total of \$36, which they have not cashed. They claim that the \$36 did not cover amounts paid for products for which they no longer had identifying information, although they do not allege what those products are. They did not request a refund for the adult products. They seek replacement, transportation, and investigation costs. Id. ¶ 43.

20. Wayne Burrell

Burrell, a Florida resident, purchased Children's Tylenol and Tylenol Plus Suspensions for between \$6 and \$7 plus tax; he has identifying information for these products. He was aware of the recall but did not become aware of the refund offer until the lawsuit, and has not requested a refund. He seeks replacement, transportation, and investigation costs. Id. ¶ 44.

21. Farlesher Murphy

Murphy, a Louisiana resident, purchased Children's Tylenol Plus and two forms of Children's Tylenol, all of which

may have been recalled. She also purchased Children's Motrin for which she does not have identifying information. For each of the products she spent between \$5 and \$6. She was aware of the recall but not the refund offer until becoming involved in the suit. She has not requested a refund. She seeks replacement, transportation, and investigation costs. Id. ¶ 45.

22. Jennifer DeGroot

DeGroot, an Ontario resident, purchased Children's Motrin Suspension 120 mL for between CAD 8-9. Her daughter "suffered a serious adverse reaction" to that product, requiring hospitalization. She learned about the recall from a news broadcast in April or May 2010. Her husband requested a refund check from the website in May 2010, and received one for CAD 12. In addition, she and her husband contacted the defendants to inquire about the reason for the recall, and the defendants asked them to return the unused portion of the product for testing. The DeGroots agreed on the condition that a report on the defendants' findings be provided to them, but the defendants' representative said that was unlikely, as they were probably not going to test the product or send them results if they did.

Twice, the DeGroots received packages in which to return the product, which they declined to do. Ms. DeGroot seeks replacement, transportation, and investigation costs as well as medical expenses related to her daughter's ingestion of the

product and adverse reaction. Id. ¶ 46.

23. Other "Absent Class Members"

The SAC also includes a series of allegations of physical injuries suffered by seven "absent class members" who are identified by initials only. They suffered seizures, gastrointestinal hemorrhaging, rashes, and vomiting. SAC ¶¶ 47-53. The defendants have moved to strike these averments from the SAC because these individuals are not asserting claims. The Court concludes that these allegations are irrelevant to the named plaintiffs' claims for economic injury and will not consider them.

E. Claims Asserted in the SAC

The plaintiffs name J&J, McNeil, Weldon, Goggins, Crane, and Luther as defendants. They assert claims for violations of the consumer fraud laws of fourteen states (Count I); violations of RICO, mail and wire fraud, and obstruction of justice (Count II); violations of the Magnuson-Moss Warranty Act (Count III); Strict Products Liability - Manufacturing Defect (Count IV); Strict Products Liability - Failure to Warn (Count V); Breaches of the Implied Warranties of Merchantability and Fitness for a Particular Purpose (Count VI); Negligence (Count VII); Negligent Misrepresentation/Fraud (Count VIII); Conspiracy, Concert of Action and Aiding and Abetting (Count IX); Unjust

Enrichment (Count X); and Declaratory Relief (Count XI).

III. Discussion of the Motion to Dismiss¹⁶

The defendants argue that the plaintiffs have still failed to demonstrate that they have suffered an injury in fact, depriving them of standing to bring their claims. The plaintiffs' theory of standing can be summarized as follows: each named plaintiff has suffered economic loss by purchasing defendants' drugs for an inflated price because the defendants concealed the quality control issues affecting the plants where the products were manufactured. See Pl. Opp. 9.

The plaintiffs assert that they have moved beyond the conclusory "serious problems" allegations of the CAC and instead

¹⁶ A motion to dismiss made under Rule 12(b)(1) "may be treated as either a facial or factual challenge to the court's subject matter jurisdiction. In reviewing a facial attack, the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff. In reviewing a factual attack, the court may consider evidence outside the pleadings. Gould Elecs. v. United States, 220 F.3d 169, 176 (3d Cir. 2000) (citing Mortensen v. First Fed. Sav. & Loan Ass'n, 549 F.2d 884, 891 (3d Cir. 1977)).

The defendants' argument is that even if the averments of the SAC are true, no plaintiff has suffered a constitutionally cognizable injury, given the existence of the recall and the fact that no plaintiff has alleged that a non-recalled product was defective as to them. Thus, the Court treats the instant motion as a facial attack, and accepts all allegations of the SAC as true for purposes of the motion. That a purchaser of any product recalled at the consumer level is entitled to a refund or coupon is conceded by the defendant and undisputed by the plaintiff. See Tr. Hr'g 1/19/12 at 7:20-23 ("[T]he mere fact of the recall, we would agree, entitles plaintiffs either to a cash refund or a coupon, at their preference.").

narrowed the scope of "Subject Products" to those that "(1) were implicated by the FDA reports, (2) were the subject of some recall by Defendants and (3) are now no longer being manufactured, due to the shutdown of McNeil manufacturing facilities." Id. at 11. As an initial matter, this does not appear to the Court to be accurate. Although many of the "Subject Products" identified in Exhibit A to the SAC were subject to recall, many others were not. The SAC collapses the categories of "Recalled Subject Products" and "Subject Products" that appeared in the CAC into a single category, the unifying characteristic being that they all were manufactured at a facility cited by the FDA for cGMP issues.

The plaintiffs argue that "[l]oss in value of the Subject Products is sufficient to confer standing." Id. at 14. This theory was rejected by the Court in its earlier opinion. See Mem. Op. 33-36. No named plaintiff either has been refused a refund for a product that was recalled or alleged that a non-recalled product is defective as to them. As a result, no named plaintiff has suffered an injury in fact traceable to the conduct of the defendants sufficient to confer standing on the plaintiffs and subject matter jurisdiction on the Court. Therefore, the Court will grant the motion to dismiss in its entirety.

A. Article III Standing Generally¹⁷

The doctrine of standing derives from Article III of the United States Constitution, which limits the jurisdiction of federal courts to "Cases" and "Controversies." U.S. Const. Art. III, § 2. The "irreducible constitutional minimum" of standing requires that a plaintiff establish three elements in order to invoke federal jurisdiction: injury, causation, and redressability. First, the plaintiff must have suffered an injury in fact, which is an invasion of a legally protected interest that is (a) concrete and particularized, and (b) actual or imminent. Second, the plaintiff must establish a causal connection between the injury and the conduct complained of. Third, the plaintiff must establish that it is likely, as opposed to merely speculative, that the injury will be "redressed by a favorable decision." Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992) (citations omitted).

These requirements are the "bedrock" that "protects the system of separated powers and respect for the coequal branches by restricting the province of the judiciary to 'decid[ing] on the rights of individuals.'" In re Schering Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 244 (3d Cir.

¹⁷ Given the Court's focus in its earlier opinion on standing and the fact that the requirements of Article III have not changed since that memorandum issued, many of the general principles articulated in the July decision are restated here, largely without alteration. See Mem. Op. 21-23.

2012) (quoting Marbury v. Madison, 5 U.S. (1 Cranch) 137, 170 (1803)). The plaintiff bears the burden of establishing the existence of standing by alleging facts that plausibly establish the three elements described above. Id.

Standing also applies in the class action context. "Even named plaintiffs who represent a class must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent." Lewis v. Casey, 518 U.S. 343, 357 (1996). If no named plaintiff establishes standing, none may seek relief on behalf of other members of the class. O'Shea v. Littleton, 414 U.S. 488, 494 (1974).

A plaintiff generally must establish that standing exists with respect to each claim made in a suit. However, in the instant suit the same injuries--overpayment and costs associated with replacement--are alleged with respect to all claims. A claim-by-claim analysis of standing is thus unnecessary. See Toll Bros., Inc. v. Twp. of Readington, 555 F.3d 131, 139 n.5 (3d Cir. 2009).

In addition, the Court of Appeals for the Third Circuit recently held that a district court must apply a "plausibility" standard when analyzing whether the factual allegations of a complaint, taken as true, show that the plaintiff possesses

Article III standing: "With respect to 12(b)(1) motions in particular, the plaintiff must assert facts that affirmatively and plausibly suggest that the pleader has the right he claims (here, the right to jurisdiction), rather than facts that are merely consistent with such a right." In re Schering Plough, 678 F.3d at 244 (quoting Stalley v. Catholic Health Initiatives, 509 F.3d 517, 521 (8th Cir. 2007)).

Injury and causation are the centrally disputed issues in the instant case (and redressability is not briefed by the parties). With respect to injury in fact, the plaintiff must allege some form of injury as a result of the defendant's conduct that is "distinct and palpable," not "abstract or conjectural or hypothetical." Danvers Motor Co. v. Ford Motor Co., 432 F.3d 286, 291 (3d Cir. 2005). Economic harm in the form of damages is a "paradigmatic" form of injury in fact and will generally support standing unless such a theory is "totally fanciful." Id.

The defendant also must have caused the plaintiff's injury. Unless that injury "fairly can be traced to the challenged action" of the defendant, standing does not exist. Whitmore v. Arkansas, 495 U.S. 149, 155 (1990); Winer Family Trust v. Queen, 503 F.3d 319, 325 (3d Cir. 2007). This requirement is met if the plaintiff alleges facts showing a "'substantial likelihood' that [the] defendant's conduct caused [the plaintiff's] harm." Pub. Interest Research Grp. v. Powell

Duffryn Terminals, 913 F.2d 64, 72 (3d Cir. 1990) (quoting Duke Power Co. v. Carolina Env'tl. Study Grp., Inc., 438 U.S. 59, 75 n.20 (1978)).

B. Injury and Causation in the Instant Case

The plaintiffs have not alleged facts showing that they have suffered injuries fairly traceable to the defendants' conduct. Although the SAC abandons the distinction drawn in the CAC between "Subject Products" and "Recalled Subject Products," that distinction is central to the standing analysis.

1. Non-Recalled Products

As with the original pleading, no plaintiff in the SAC can establish standing based on the purchase of products that were not recalled and that are not alleged to have been defective.¹⁸ The Court discussed this category of products at length in its earlier opinion, finding that "conclusory allegations" regarding the "serious problems" affecting the products they purchased were insufficient to establish injury. No plaintiff alleges facts that, if proven, would show that a non-recalled "Subject Product" was actually defective as to them, i.e., that it failed to perform as intended. The failure to be reimbursed for products that were not defective is "insufficient

¹⁸ This group includes Taylor, Munn & Munn, Scott, Pack, Renz, Michaud, Rivera, Angel, Nguyen, Varner, and Murphy.

to show an invasion of a legally protected interest.” Mem. Op. 27 (citing Danvers Motor Co., 432 F.3d at 291; Rivera v. Wyeth-Ayerst Labs., 283 F.3d 315 (5th Cir. 2002)).

The plaintiffs claim that their losses arose at the time of sale because they paid premium prices for products that were manufactured at facilities with quality control problems, and therefore they need not allege that the Subject Products were defective as to them because they were deprived of the “benefit of their bargain.” Pl. Opp. 12-15. The cases the plaintiffs cite for this proposition are distinguishable because all of them involve a contract between the parties; some of those courts explicitly disavow their holdings when applied to the circumstances of the instant case.

For example, the plaintiffs cite Coghlan v. Wellcraft Marine Corporation, 240 F.3d 449 (5th Cir. 2001). The district court in Coghlan had characterized the suit as a “no-injury products liability case” and dismissed for failure to state a claim because the plaintiffs could not allege damages, but the appeals court reversed. The Fifth Circuit held that an allegation of a defective product was sufficient to state a claim for damages in a contract setting, because it was required to accept the plaintiffs’ averment that they had contracted for a fiberglass boat but were given something different and thus deprived of the benefit of their bargain. Id. at 455. But the

Coghlan court explicitly distinguished a “no-injury products liability” case as one where the defendant places a

dangerous/defective product in the stream of commerce. . . . The striking feature of a typical no-injury class is that the plaintiffs have either not yet experienced a malfunction because of the alleged defect or have experienced a malfunction but not been harmed by it. Therefore, the plaintiffs in a no-injury products liability case have not suffered any physical harm or out of pocket losses. . . . [T]he no-injury approach to product litigation has been rejected in several recent decisions.

Id. at 455 n.4. (citing Briehl v. Gen. Motors Corp., 172 F.3d 623 (8th Cir. 1999)).

The Fifth Circuit reiterated its understanding of that distinction in Rivera, a case with facts similar to the instant case. The Rivera court found standing lacking because the plaintiffs, purchasers of the Wyeth drug Duract, had not stated a cognizable injury because they failed to allege that the drug was defective as to them. The court explicitly distinguished Coghlan as sounding in contract and characterized the plaintiff’s attempt to invoke the “benefit of the bargain” holding in that case as “artful pleading.” The court noted that seeking “out-of-pocket expenditures” and benefit-of-the-bargain damages was not appropriate in a tort action.¹⁹ 283 F.3d at 320-21.

¹⁹ The Rivera decision was also discussed in Cole v. General Motors Corp., 484 F.3d 717 (5th Cir. 2007), a case cited by the plaintiffs, where the Fifth Circuit found standing among a group of purchasers of cars with defective airbags (that had not yet manifested the defect) alleging injury at the time of purchase

The reasoning of Rivera is persuasive. The Court discussed Rivera in its earlier opinion and the defendants again cited it in their motion to dismiss. The plaintiffs did not discuss the case at all until oral argument, when Rivera was dismissed as "irrelevant" because the allegations of the instant case go "so far beyond" mere FDA citations.²⁰ Tr. Hr'g 1/19/12 at 28.

and resale. It again held that "benefit of the bargain" no-injury cases were limited to contract. Id. at 722-23.

²⁰ Another case cited by the Court in its earlier opinion and referred to by the defendants but again unmet by the plaintiffs is Myers-Armstrong v. Actavis Totowa, LLC, No. 08-4741, 2009 WL 1082026 (N.D. Cal. Apr. 22, 2009). In Myers-Armstrong, the court concluded that the plaintiff did not state a cognizable injury when seeking economic damages resulting from cGMP issues at the plant manufacturing the drug she purchased because she had not alleged that the drug did not work as intended or that she rationally feared future harm. See id. at *4 (describing the plaintiff's claim of injury as one made "on the theory that the pills came from a source of uncertain quality").

The Court can find no other tribunal accepting the plaintiffs' theory here, at least in the pharmaceutical context. See, e.g., Ironworkers Local Union 68 v. Astrazeneca Pharms., 634 F.3d 1352, 1363 (11th Cir. 2011) (citing Rivera and concluding that to demonstrate economic injury, a plaintiff must allege that "the drug was unsafe or ineffective for its prescribed use"); Loreto v. Procter & Gamble Co., 737 F. Supp. 2d 909, 922 (S.D. Ohio 2009) (no loss when the "consumer gets what he/she paid for"); Heindel v. Pfizer, Inc., 381 F. Supp. 2d 364, 380 (D.N.J. 2004) (no injury where plaintiffs failed to allege drug was defective as to them); In re Rezulin Prods. Liab. Litig., 210 F.R.D. 61, 68 (S.D.N.Y. 2002) (the "patients got their money's worth and suffered no economic injury" where they were otherwise unharmed). See also Whitson v. Bumbo, No. 07-5597, 2009 WL 1515597, at *2 (N.D. Cal. Apr. 6, 2009) (no standing where the plaintiff had not alleged any harm resulting from inadequate warnings on the child seat she herself purchased).

The plaintiffs suggest that two recent cases from the Ninth Circuit, one at the trial level and one at the appellate level, support their theory of time-of-sale economic injury. Pl. Opp. 14 (citing Maya v. Centex Corp., 658 F.3d 1060 (9th Cir. 2011); In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig., 790 F. Supp. 2d 1152 (C.D. Cal. 2011)). The Maya plaintiffs alleged that misrepresentations as to neighborhood stability rendered their homes worth less than they paid at the time of sale. The court accepted the time-of-sale injury theory and specifically relied on a series of Supreme Court decisions holding that decreased home value is a cognizable injury under Article III. Maya, 658 F.3d at 1070-71 (citing Friends of the Earth, Inc. v. Laidlaw Enviro. Servs. (TOC), Inc., 528 U.S. 167, 183-84 (2000) (plaintiff need not sell her home in order to demonstrate diminution in value); Gladstone Realtors v. Vill. of Bellwood, 441 U.S. 91, 110-11 (1979)). Indeed, the Maya and In re Toyota courts accepted the plaintiffs' "market devaluation" theory to find injury in fact, as the ability of those plaintiffs to recoup their outlays had been impaired presently through a reduction in resale value. Maya, 658 F.3d at 1071 ("convincing evidence that the economic value of one's home has declined as a result of the conduct of another certainly is sufficient under Art[icle] III") (quoting Gladstone Realtors, 441 U.S. at 115); In

re Toyota, 790 F. Supp. 2d at 1166 (concluding that the economic loss was "actual or imminent" because the plaintiffs had alleged economic loss of trade-in value through other evidence).

Unlike the plaintiffs in Maya and In re Toyota--but like those in Rivera--the plaintiffs here rely upon the experiences of other individuals to establish that the drugs they purchased were defective. This they cannot do. The injury complained of must have been injured "in a personal and individual way." Lujan, 504 U.S. at 560 n.1. The fact that other persons suffered adverse effects, or that the defendants recalled some products that were manufactured in the same facility as the drugs they purchased, does not suffice to establish injury in fact as to this group. The Court declines the plaintiffs' implicit suggestion to expand such "no-injury products liability" claims beyond the contract context or where non-conclusory allegations of diminution in value are made. No plaintiff who purchased a non-recalled product has stated a cognizable Article III injury.

2. Recalled Products

For products that were recalled, all named plaintiffs are now aware of the recall program, and no plaintiff has alleged that any refund sought has been or will be inadequate to compensate them fully for all recalled products they purchased. Instead, counsel has pointed to reports of inadequacies in the

program from persons other than the plaintiffs. As with the plaintiffs who purchased non-recalled products, this group may not rely on the experiences of other individuals to establish injury. The defendants have offered the plaintiffs a cash refund as to all products that have been recalled. A named plaintiff must allege facts showing that he or she personally suffered economic loss as a result of an inadequate recall to state a cognizable injury on the basis of a recalled product.

The Court accepts that the mere existence of a refund offer is not sufficient to defeat standing. See In re Mattel, Inc., Toy Lead Paint Prods. Liab. Litig., 588 F. Supp. 2d 1111 (C.D. Cal. 2008). Although the defendants' refund program cannot defeat standing on its own, the absence of any allegation that the refund offer was insufficient based on the experience of a named plaintiff is fatal. See Lujan, 504 U.S. at 560 n.1 (an injury "must affect the plaintiff in a personal and individual way"); Warth v. Seldin, 422 U.S. 490, 501 (1975) ("[A] plaintiff must allege a distinct and palpable injury to himself").²¹

The plaintiffs emphasize their allegations regarding

²¹ The Court discussed Mattel in its earlier opinion, noting that the plaintiffs had not offered factual allegations of "any harm arising from the recall that was not, or could not be, adequately resolved by the recall." Mem. Op. 34; see also id. n.26 (noting that "the plaintiffs must still show that the remedy offered by the defendants was somehow inadequate as to them"). The same deficiency plagues the complaint as amended.

the prices McNeil used in the refund program to highlight its alleged inadequacy, including the "average retail price" language in the McNeil Q&A made available to consumers, and the round (and variable) numbers used in an internal document distributed to administrators of the refund program. See, e.g., Tr. Hr'g 1/19/12 at 47-48. But these allegations do not support the concrete and particularized injury required by Article III. Critically, no plaintiff has alleged that he or she sought a refund for recalled products and was denied one, or that any refund actually received did not fully cover the price paid for a recalled product.²²

The plaintiffs who allege that they purchased recalled products may be divided into two groups.

a. Purchasers of Recalled Products Who Have Sought a Refund

This subset of the named plaintiffs includes Daniel Pack, Justin Michaud, Emile & Amber Roberson, John Smith, Jennifer DeGroot, and possibly Landy Nguyen.

Pack alleges that at the time of his initial refund

²² At oral argument counsel offered the experience of Spivey as a purported example of an insufficient refund. Spivey paid between \$8 and \$9 for Children's Motrin, but internal J&J documents mention an average retail price of \$6.89. This, according to counsel, demonstrates that she would not be fully compensated by a refund and is why she did not request one. Tr. Hr'g 1/16/12 at 52-53. However, this allegation does not appear in the SAC. Rather, Spivey is alleged to have declined to seek a refund because it "was too much effort." SAC ¶ 25.

request, he did not understand that he could request refunds for additional recalled products. He received a refund for the products for which he submitted a request and does not allege that that offer was inadequate as to those products; he merely alleges that the cash he received does not cover the purchase price of all the products he purchased. SAC ¶ 32.

Michaud received a refund of \$13 that covered his purchase of one bottle of recalled Children's Zyrtec for which he had identifying information. He argues that because he purchased one bottle per month dating back to 2008, he has not been fully compensated. He does not allege that the Zyrtec he purchased earlier was defective or that \$13 did not cover the purchase price of the recalled bottle of Zyrtec. Id. ¶ 34.

The Robersons requested refunds for four children's products, and received \$36 in two checks. They have not alleged that the \$36 does not cover the full purchase price of those children's products, but argue that they have not been fully compensated because those checks do not cover "any of the purchase price for Subject Products that the Robersons no longer had identifying information [sic]." ²³ They have not requested a refund for adult products, nor have they alleged that those products were defective as to them. Id. ¶ 43.

²³ The Court discusses the plaintiffs who discarded the products they purchased below in Section III.B.3.

Smith purchased Children's Tylenol that had been recalled and either requested a replacement coupon or was offered one and accepted it. He has not yet received that coupon. Id.

¶ 38. The terms of the McNeil coupon offer are that consumers who accept coupons will be given them once the product becomes available again. SAC Ex. I at McNeil-MDL-0000029. Smith has not alleged that the product is available again at retail, that McNeil will not be sending him a coupon when it is available, or that the coupon McNeil will send him will not fully compensate him for the product. If his injury is not having the coupon at present, his injury is the result of his own decision, not any action on the part of the defendants.

Jennifer DeGroot sought a refund for her purchase of a recalled product, and received one. She does not allege that she was not fully compensated by the cash refund she received; indeed, it "is believed to have covered the full purchase price of the Subject Products, including sales taxes." Id. ¶ 46.

Landy Nguyen may be part of this group because she alleges that she did make two attempts to inquire about the recall or request a refund but suggests she was unable to make herself understood due to her Asian accent. The "[d]efendants' representative asked to call back at a later time [sic]" the first time, and the second time she called, Nguyen felt that "the representative was hiding something, and that she was getting the

run-around.” Id. ¶ 39. The defendants argue that this does not support a claim that she suffered an economic injury, and that she can “easily remed[y]” her harm by using the recall website or having a family member request the refund by phone.

None of these plaintiffs has suffered an economic injury that is traceable to the conduct of the defendants. All refund requests submitted for recalled products by Pack, Michaud, the Robersons, and DeGroot were satisfied. Plaintiffs’ counsel conceded at oral argument that Smith elected to receive the coupon in lieu of cash. Smith has not alleged that the coupon, which by the terms of the offer will not issue until the product is available at retail, will never be issued or is otherwise without value. Nguyen’s failure to receive a refund cannot be traced to the conduct of the defendants; she has not been denied a refund and is free to request one through means by which she is able to make herself understood.

b. Purchasers of Recalled Products Who Are Eligible for but Have Not Sought a Refund

These plaintiffs have alleged facts that could demonstrate that they are entitled to a refund.²⁴ However, for

²⁴ In their moving papers, the defendants define this group by referencing those plaintiffs who have identifying information that makes clear that they could be entitled to a refund if they requested one. Liberally interpreting the plaintiffs’ allegations, the Court includes in this group any plaintiff who purchased a product that may have been subject to a recall but who has not requested a refund from the defendants. Under that

whatever reason, these plaintiffs have elected not to seek one. Some of these plaintiffs have alleged that they have not sought one because of "red tape" or "too much effort" involved in securing a refund; others believed that they were only able to seek a refund for a limited number of recalled products; one plaintiff had difficulty making herself understood and ceased attempting to seek a refund. No fact alleged by any of these plaintiffs plausibly establishes that they suffered an injury that is fairly traceable to the conduct of the defendants.

Where a plaintiff's allegations of injury require such a speculative chain of inferences, the plaintiff does not have standing. See Johnson v. Guhl, 357 F.3d 403 (3d Cir. 2004). In Johnson, the plaintiffs were Medicaid applicants denied benefits because New Jersey deemed their spouses' annuity trusts to be assets for purposes of eligibility determinations. During the pendency of proceedings in district court, New Jersey established procedures, required by federal law, allowing those deemed ineligible to apply for an "undue hardship" hearing that might have resulted in the payment of benefits despite technical ineligibility. Id. at 411-12.

The state made the plaintiffs aware of the availability

standard, this group includes Spivey, Taylor, Thrasher, Munn & Munn, Coleman, Carroll, Pack, Renz, Michaud, Rivera, Angel, Roselli, McDaid, Mannara, Varner, Roberson & Roberson, Burrell, and Murphy.

of such a hearing. The plaintiffs argued that those procedures did not comply with Medicaid regulations requiring "timely process" in undue hardship hearings, but no plaintiff had attempted to apply for one. The Third Circuit dismissed the plaintiffs' claims for lack of standing, finding that no plaintiff had suffered any injury or had any "basis to believe that New Jersey would not have timely processed their request." Id. at 412.

The plaintiffs argue that Johnson v. Guhl is inapposite because "in the instant case all Plaintiffs have not been offered full cash refunds (including all taxes) with no string [sic] attached." Pl. Opp. 19. They argue that "testing the system" here is pointless because other plaintiffs have been denied full refunds (i.e., have not received refunds for products that are not confirmed to be subject to recall). To find that these plaintiffs have been injured with respect to their purchases of recalled products, the Court would have to assume that if the plaintiffs requested a refund, they would be denied one, or that the refund offered would be inadequate to make them whole. When such speculation is required as to the causal link between the behavior of a defendant and an injury of the plaintiff, no standing exists. See In re Schering Plough, 678 F.3d at 248 (holding that "pure conjecture" was required to conclude that the defendants' conduct ultimately caused the plaintiff injury, and

therefore no standing existed).

As with other groups, to the extent that this set of plaintiffs relies on the experiences of others to argue that seeking a refund would be pointless, such allegations are inadequate because the named plaintiffs must establish an injury that is particularized to them. Even if relying on the experiences of other plaintiffs could serve as the basis for standing, these plaintiffs have not even alleged that their awareness of potentially inadequate refund offers caused them not to seek a refund; this argument came in the form of attorney speculation at oral argument. Tr. Hr'g 1/16/12 at 47-48. This group of plaintiffs therefore also lacks standing.

c. "Incidental and Consequential Damages"

The plaintiffs argue that their injuries in fact go beyond the purchase price and taxes of the products they purchased, and assert that they possess standing on the basis of injuries sustained in the form of "transportation expenses . . . time spent investigating the recall and speaking to medical professionals/pharmacists," and other incidental costs related to the plaintiffs' having learned of the recall. They refer to such injuries as "incidental and consequential damages." Pl. Opp. 46, 49. These outlays are the result of the plaintiffs' own choices and are not fairly traceable to the actions of the defendants. Cf. Alston v. Advanced Brands & Imp. Co., 494 F.3d 562, 565 (6th

Cir. 2007) (no standing where injury is caused not by the defendants' conduct but instead by third parties "accountable for their own actions"); Frank Krasner Enters., Ltd. v. Montgomery Cnty., Md., 401 F.3d 230, 235 (4th Cir. 2005) (the plaintiff may not satisfy "one or more of the essential elements of standing . . . [based on] unfettered choices made by independent actors"). The plaintiffs undertook these actions on their own and any costs associated with them are, therefore, not traceable to the defendants. See 13A Charles Alan Wright, Arthur R. Miller, & Edward R. Cooper, Federal Practice and Procedure § 3531.5 at 354-60 & n.68 (3d ed. 2008) (although self-inflicted injury may serve as the basis for standing, where injury is "almost solely . . . attributable to the plaintiff" or suffered "on the basis of purely speculative fears," it may not); see also Pennsylvania v. New Jersey, 426 U.S. 660, 664 (1976) (state lacked standing where injury was a result of its own legislature's decision to credit taxes paid elsewhere). The expenses termed "incidental or consequential damages" here may not confer standing.

3. Plaintiffs Who Discarded Products

Many plaintiffs have alleged that they discarded the products that they purchased and therefore lack the information required to determine whether they were recalled. No plaintiff in this group has alleged that any product they discarded was

adulterated or ineffective as to them. Some plaintiffs aver that they lack information due to discarding the products "because of the recall" while others merely aver that they discarded the product.²⁵ No plaintiff who has alleged that he or she discarded products "because of the recall" alleges that he or she did so because of any instructions given by the defendants. As with plaintiffs who purchased recalled products but did not seek a refund, any injury suffered by this group is not traceable to the defendants' conduct.²⁶

At oral argument, counsel suggested that "normal consumer behavior" led these plaintiffs to discard products

²⁵ Those who discarded "because of the recall" include named plaintiffs Taylor, Coleman, Carroll, Pack, Renz, Angel, Nguyen, Varner, and Murphy. (However, Angel also avers that her mother instructed her to "get rid of the products she had in her possession." SAC ¶ 36.)

Those who merely discarded the products (and do not aver that it was because of the recall) are named plaintiffs Scott, Michaud, and Mannara.

Additionally, the Robersons make averments that they were unable to seek a recall for some of the products they purchased because they "no longer had identifying information." The standing analysis applicable to this group also applies to them.

²⁶ A case with similar facts is Meaunrit v. Pinnacle Foods Group, LLC, No. 09-4555, 2010 WL 1838715 (N.D. Cal. May 5, 2010). In Meaunrit, the plaintiffs were purchasers of frozen pot pies who alleged that when the meals were heated according to instructions, they still posed a risk of food-borne pathogens. Although no plaintiff alleged that he had been injured by eating an unsafe meal, recovery was sought for losses related to the disposal of the meals; the plaintiffs asserted they were deprived of the benefit of their bargain (i.e., a safe-to-consume meal). The court concluded that any injury suffered by a plaintiff could not be traced to the defendants' conduct because those injuries were self-inflicted. Id. at *3.

because J&J advised that recalled products were not safe to use, or that consumers would naturally discard products they learned "through media reports" had been recalled. Tr. Hr'g 1/16/12 at 45, 63. If, however, no plaintiff discarded a product on the instructions of a defendant, the Court would have to speculate as to how the actions of the defendants caused the injury a plaintiff suffered when he or she discarded the product. See In re Schering Plough, 678 F.3d at 248. The facts as alleged do not give rise to a plausible inference that these plaintiffs' injuries are fairly traceable to the conduct of the defendants. These plaintiffs thus also lack standing.

In sum, no named plaintiff has alleged facts that plausibly demonstrate that he or she possesses standing under Article III and is thus able to invoke the jurisdiction of the Court. When, in the setting of a putative class action, no named plaintiff possesses standing, none may assert claims on behalf of others. Lewis, 518 U.S. at 357.

The Court will grant the defendants' motion to dismiss. Like the CAC before it, the SAC fails to assert any claim by a plaintiff who has suffered an injury in fact that is fairly traceable to the conduct of the defendants. The Court's dismissal will therefore be with prejudice.

An appropriate order shall issue separately.